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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 11 2005

Michael Lelah, Ph.D.
Technical Director
NOW Foods
395 S. Glen Ellyn Road
Bloomington, Illinois 60108

Dear Dr. Lelah:

This is in response to your letter of June 30, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NOW Foods is making the following claims, among others, for the product **AHCC**®:

“[A]HCC® supports immune system function through its ability to enhance...NK (Natural Killer) Cell activity...NK cell number is dramatically increased in the presence of viruses.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, such as infectious viral diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SN' with a long horizontal stroke extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Chicago District Office, Office of Compliance, HFR-CE640



We Make Quality Affordable

June 30, 2005

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements
Division of Nutritional Programs and Labeling
200 C Street SW
Washington, DC 20204

JUL 18 2005

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of AHCC[®], a dietary supplement.

Statements being made in the labeling of AHCC[®]:

- (1) AHCC[®] is a proprietary extract produced from specially cultivated and hybridized mushrooms. According to extensive research in humans, as well as numerous non-clinical studies, AHCC[®] supports immune system function through its ability to enhance macrophage and NK (Natural Killer) Cell activity. NK cells and the intercellular mediators they produce are critical for the maintenance of healthy cell cycle function. In addition, NK cell number is dramatically increased in the presence of viruses. AHCC[®] has also been shown to possess antioxidant properties, and supports healthy liver function.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Michael Lelah, Ph.D.
Technical Director
NOW Foods
395 S. Glen Ellyn Rd.
Bloomington, IL 60108

Michael Lelah

#1297

05-4518